Message

From: Lindstrom, Andrew [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=04BF7CF26AA44CE29763FBC1C1B2338E-LINDSTROM, ANDREW]
Sent: 4/24/2017 1:45:52 PM
To: Libelo, Laurence [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=da33642e6438407daf4c35afe870046b-Libelo, Laurence]
Subject: RE: GenX-related studies

Laurence,

Thank you for getting back to me on this. I figured they need to be all inclusive and redacted and all but I would have thought that other folks would have dug them up and looked at them by now. But who's got time for that, eh?

Hey, speaking of that, chek out this new work form Ian Cousin's group:

http://www.diva-portal.org/smash/record.jsf?pid=diva2%3A1085404&dswid=-462

Depending on how you look at it, GenX is more toxic than PFNA and PFOA.

3.4.2 Potency ranking of legacy PFCAs and alternatives

The rationale behind the use of shorter chain homologues and other fluorinated alternatives to replace PFOA is based on a lower B and T.[188] In terms of potency, the following ranking has been established based on administered dose and its effect on the liver weight of male rats: PFNA>PFOA>GenX>PFBA>PFHxA (see Figure 8). **Paper IV** investigated to what extent this ranking is attributed to differences in pharmacokinetics among the substances. As shown in Figure 8, the ranking changes to PFNA≈GenX>PFOA>PFHxA>PFBA when considering serum AUC_∞ and

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GenX>PFNA≈PFOA≈PFHxA≈PFBA when considering liver AUC_∞. The results were correlated with the serum and liver distribution and the elimination half-life. Due to the high bioaccumulation potential of PFNA and, to a lesser extent, PFOA, the dose required to reach a certain level in serum or liver is low compared to short-chain PFCAs. PFOS and PFBS were also assessed but results were inconclusive since no significant effect on the liver weight was observed for PFBS.[55] These findings indicate that toxicokinetics is an important parameter in the toxicity of PFAAs and that alternatives to legacy PFAAs could likely be intrinsically as potent as their predecessors. More attention should be placed on GenX, which was also studied in **Paper III**. According to both studies, GenX is as persistent and mobile as PFOA and could possibly be more intrinsically potent than PFOA.

So you haven't responded to my questions about you new boss. Now folks are saying her appointment is a conflict of interest. Who knew that might happen?
And what about that PMN backlog? That's where it gets real.

Thank you,

Andy

From: Libelo, Laurence
Sent: Monday, April 24, 2017 9:30 AM
To: Lindstrom, Andrew <Lindstrom.Andrew@epa.gov>
Subject: RE: GenX-related studies

Hi Andy,

These sound like typical studies we get in support of new chemicals. I am surprised that they are public. In most cases the companies claim them as CBI and only redacted versions that have limited info are released.

I believe these were reviewed by OPPT/RAD toxicologists when they were submitted with the PMN.

The large documents are because we require that all raw data be included. This often means everything down to copies of lab notes, temp logs etc.

This is pretty much what we get for these studies.

I look at the fate and transport studies. I generally don't see the tox studies.

Laurence

From: Lindstrom, Andrew
Sent: Friday, April 21, 2017 11:03 AM
To: Libelo, Laurence <Libelo.Laurence@epa.gov>
Subject: GenX-related studies

Laurence,

Our library was finally able to get copies of the following GenX-related studies:

M.C. Haas, A 28-day Oral (Gavage) Toxicity Study of H-28397 in Rats with a 28-day Recovery (Study No. Wil-189205), WIL Research Laboratories, LLC,Ashland, OH, 2008.

M.C. Haas, A 90-day Oral (Gavage) Toxicity Study of H-28548 in Rats with a 28-day Recovery (Study No. Wil-189216), WIL Research Laboratories, LLC,Ashland, OH, 2009.

They're both digitized copies of enormous documents, the first being over 1000 pages (over 200 MB) and the second over 2000 pages (over 400 MB).

Is this normal?

Regarding the long time that it took for our librarians to obtain these documents, they write the following:

Hi Andrew,

The papers were difficult to access, because the company which conducted the initial research appeared to have changed names twice before submitting the research to the Docket Office. To locate them we first had to contact the company who provided us with the premanufactured notification numbers for the chemicals. From there we were able to track down its CAS numbers and a docket number, which allowed us to contact the Docket Office and request the reports. Since both reports were over 1,000 pages, the Docket Office mailed us a CD which the PDFs were downloaded onto.

As far as whether or not more information about the compound is confidential, it is my understanding that EPA contractors are not required to publically publish information unless it must be a part of the Docket. Especially for older documents, it may not be available online because it was never digitized. Usually in these situations documents are digitized as they are requested, so it is very possible that there was never a need to make the materials publically available.

This is new research to me, but here is the website where I found most of my information about the PMN process which I hope can be of some help to you as well: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/epas-review-process-new-chemicals

To find the documents we used ChemView and the Chemical Data Access Tool where we could search by the PMN number:
https://java.epa.gov/chemview
https://java.epa.gov/oppt_chemical_search/

And folks talk about secret science. That's kind of what this sounds like to me.

I get the impression that almost nobody has ever seen these documents - right? I've asked my toxicologist to look these over to see if they see anything interesting.

Has any EPA toxicologist ever seen these? What do you think?

Thank you,

Andy